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10/655,878

09/05/2003

Richard Somberg

03-772

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20306

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04/01/2008

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EXAMINER

WOOD, AMANDA P

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

04/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/655,878 | Applicant(s) SOMBERG ET AL. | |
| | Examiner AMANDA P. WOOD | Art Unit 1657 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-18, 22 and 24-47 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 27-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-17, 22 and 24-26 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response and amendments filed 28 November 2007 have been received and entered.

Claims 1-11, 14-18, 22, and 24-26 have been examined on the merits.

Claims 12 and 27-47 were previously withdrawn by the Examiner as being drawn to inventions non-elected with traverse, in the reply filed on 14 April 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Withdrawn Rejections

In view of Applicant's amendments to the claims, the rejection under 35 USC § 112, first paragraph and second paragraph have been withdrawn.

Claim Objections

Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 14-17, 22, and 24-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Crouch et al (2001) in view of Simpson et al (J. Biolum and Chemilum 1991), for the reasons set forth in the previous Office Action.

Response to Arguments

Applicant's arguments filed 28 November 2007 have been fully considered but they are not persuasive. In particular, Applicant argues that the cited references do not teach adding a single reagent to the transferase reaction mixture which simultaneously stops the transferase reaction and initiates the bioluminescence reaction in one step.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the teaching of a single reagent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Since the claims do not specify that a single reagent is provided, the claims have been interpreted broadly, and therefore, the cited references read upon the instant claims. Furthermore, the Examiner notes that Applicant teaches in the instant specification at page 27 a preferred embodiment wherein the components of the reagent composition can be supplied as "two parts that are admixed shortly before use: (1) a part comprising luciferase and (2) a part comprising one or more transferase quenching agents," and therefore, the reagent provided by Applicant is not necessarily a single reagent as argued by Applicant.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant argues that each of the individual references do not provide the necessary elements of the whole invention, where it is the combination of teachings of Crouch and Simpson that provides the motivation and the obviousness for providing the reagent of the instant claims. Crouch beneficially teaches a method of detecting kinase activity by combining a kinase, ATP and substrate with luciferase and luciferin for measurement of kinase activity, whereas Simpson beneficially teaches that certain detergents actually increase the stability of luciferase and increase the luminescent signal detected from the reaction.

In response to applicant's argument that the prior art references do not teach methods for providing a reagent comprising a detergent that selectively stops ATP-dependent transferase activity while allowing for a bioluminescent reaction to occur, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Since the Simpson provides the teaching that non-ionic and zwitterionic detergents can increase reaction rates over a broad range of detergent concentrations without affecting enzyme stability, it would have been obvious to one of skill in the art at the time the invention was made to provide a reagent comprising such

detergents and firefly luciferase for the expected benefit of reducing assay costs and increasing assay sensitivity.

Claims 1-10, 14-17, 22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crouch et al (2001) in view of Simpson et al (J. Biolum and Chemilum 1991) and further in view of Briggs et al (Biochem 2000) for the reasons set forth in the previous Office Action.

Response to Arguments

Applicant's arguments filed 28 November 2007 have been fully considered but they are not persuasive. In particular, Applicant argues that the cited references do not teach adding a single reagent to the transferase reaction mixture which simultaneously stops the transferase reaction and initiates the bioluminescence reaction in one step.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the teaching of a single reagent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Since the claims do not specify that a single reagent is provided, the claims have been interpreted broadly, and therefore, the cited references read upon the instant claims. Furthermore, the Examiner notes that Applicant teaches in the instant

specification at page 27 a preferred embodiment wherein the components of the reagent composition can be supplied as “two parts that are admixed shortly before use: (1) a part comprising luciferase and (2) a part comprising one or more transferase quenching agents,” and therefore, the reagent provided by Applicant is not necessarily a single reagent as argued by Applicant.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant argues that each of the individual references do not provide the necessary elements of the whole invention, where it is the combination of teachings of Crouch and Simpson that provides the motivation and the obviousness for providing the reagent of the instant claims. Crouch beneficially teaches a method of detecting kinase activity by combining a kinase, ATP and substrate with luciferase and luciferin for measurement of kinase activity, whereas Simpson beneficially teaches that certain detergents actually increase the stability of luciferase and increase the luminescent signal detected from the reaction.

In response to applicant's argument that the prior art references do not teach methods for providing a reagent comprising a detergent that selectively stops ATP-dependent transferase activity while allowing for a bioluminescent reaction to occur, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the

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differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Since the Simpson provides the teaching that non-ionic and zwitterionic detergents can increase reaction rates over a broad range of detergent concentrations without affecting enzyme stability, it would have been obvious to one of skill in the art at the time the invention was made to provide a reagent comprising such detergents and firefly luciferase for the expected benefit of reducing assay costs and increasing assay sensitivity.

With respect to Briggs, Applicant argues that Briggs adds nothing to Crouch or Simpson that could remedy the deficiencies of these two references. The Examiner respectfully disagrees with Applicant's arguments with respect to Crouch, Simpson and Briggs. Applicant argues the deficiencies of the cited references individually where they are cited as a combination. Crouch beneficially teaches that kinases in general can be used in their invention, and the teachings of Briggs are cited to specify particular kinases important in disease progression that would be beneficial to study.

Claims 1-10, 14-17, 22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crouch et al (2001) in view of Simpson et al (J. Biol. Chem. 1991) and further in view of Lev et al (EMBO J. 1991) for the reasons set forth in the previous Office Action.

Response to Arguments

Applicant's arguments filed 28 November 2007 have been fully considered but they are not persuasive. In particular, Applicant argues that the cited references do not teach adding a single reagent to the transferase reaction mixture which simultaneously stops the transferase reaction and initiates the bioluminescence reaction in one step.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the teaching of a single reagent) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Since the claims do not specify that a single reagent is provided, the claims have been interpreted broadly, and therefore, the cited references read upon the instant claims. Furthermore, the Examiner notes that Applicant teaches in the instant specification at page 27 a preferred embodiment wherein the components of the reagent composition can be supplied as "two parts that are admixed shortly before use: (1) a part comprising luciferase and (2) a part comprising one or more transferase quenching agents," and therefore, the reagent provided by Applicant is not necessarily a single reagent as argued by Applicant.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant argues that each of the individual references do not provide the

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necessary elements of the whole invention, where it is the combination of teachings of Crouch and Simpson that provides the motivation and the obviousness for providing the reagent of the instant claims. Crouch beneficially teaches a method of detecting kinase activity by combining a kinase, ATP and substrate with luciferase and luciferin for measurement of kinase activity, whereas Simpson beneficially teaches that certain detergents actually increase the stability of luciferase and increase the luminescent signal detected from the reaction.

In response to applicant's argument that the prior art references do not teach methods for providing a reagent comprising a detergent that selectively stops ATP-dependent transferase activity while allowing for a bioluminescent reaction to occur, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Since the Simpson provides the teaching that non-ionic and zwitterionic detergents can increase reaction rates over a broad range of detergent concentrations without affecting enzyme stability, it would have been obvious to one of skill in the art at the time the invention was made to provide a reagent comprising such detergents and firefly luciferase for the expected benefit of reducing assay costs and increasing assay sensitivity.

With respect to Lev, Applicant argues that Lev adds nothing to Crouch or Simpson that could remedy the deficiencies of these two references. The Examiner respectfully disagrees with Applicant's arguments with respect to Crouch, Simpson and

Lev. Applicant argues the deficiencies of the cited references individually where they are cited as a combination. Crouch beneficially teaches that kinases in general can be used in their invention, and the teachings of Lev are cited to specify particular growth receptor family tyrosine kinases which are protooncogenes that stimulate mitogenesis which would be beneficial to study.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Please note that the examiner assigned to the instant application has changed. Accordingly, any inquiry concerning this communication or earlier communications should be directed to examiner Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on Mon-Fri 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
Art Unit 1657

/Robert B Mondesi/
Primary Examiner, Art Unit 1652
March 27, 2008